

1 KEVIN V. RYAN (CSBN 118321)  
2 United States Attorney

06-25-07 11:52 AM  
CLERK OF DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

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8 UNITED STATES DISTRICT COURT  
9 NORTHERN DISTRICT OF CALIFORNIA  
10 SAN FRANCISCO DIVISION

11 CR 03 0707

12 UNITED STATES OF AMERICA,

No.

13 Plaintiff,

VIOLATION: 21 U.S.C. §§ 331(k),  
333(a)(2) - Misbranding

14 v.

SAN FRANCISCO VENUE

15 INTERMUNE, INC.,

16 Defendant.  
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21 **INFORMATION**

22 The United States Attorney charges:

23 **INTRODUCTION**

24 At all times material and pertinent to this Information:

25 1. The United States Food and Drug Administration ("FDA") was the federal agency  
26 within the United States Department of Health and Human Services charged with enforcing the  
27 Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act") to protect the health and safety of  
28 the American public. Under the Act, a drug was misbranded if its labeling did not bear adequate

1 directions for use to permit a layperson to administer the drug safely for each of its intended uses.

2 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5.

3 2. A “prescription drug” was a drug which, “because of its toxicity or other potentiality  
4 for harmful effect, or the method of its use, or the collateral measure necessary for its use, [was]  
5 not safe for use except under the supervision of a practitioner licensed by law to administer such  
6 drug” or a drug which was “limited by an approved [new drug application] to use under the  
7 supervision of a practitioner licensed by law to administer such drug.” 21 U.S.C. § 353(b)(1). A  
8 prescription drug, by definition, could not bear adequate directions for use by a layperson.

9 3. If a prescription drug did not bear adequate directions for use for all of its intended  
10 uses, and if it was not subject to an exemption from the requirement that it bear adequate  
11 directions for use for all of its intended uses, the drug was misbranded under the FDCA. 21  
12 U.S.C. § 352(f)(1); 21 C.F.R. § 201.115.

13 4. The FDCA prohibited the doing of any act with respect to a drug, if the act was done  
14 while the drug was held for sale after shipment in interstate commerce and resulted in the drug  
15 being misbranded. 21 U.S.C. § 331(k).

#### 16 **STATEMENT OF FACTS**

17 5. Defendant, InterMune, Inc., was a biopharmaceutical company engaged in developing  
18 and commercializing therapies in pulmonology and hepatology, with its principal place of  
19 business located in Brisbane, California.

20 6. The FDA approved the use of the drug Actimmune® (interferon gamma-1b) for the  
21 treatment of chronic granulomatous disease and severe, malignant osteopetrosis.

22 7. Actimmune® was a “drug” within the meaning of 21 U.S.C. § 321(g)(1)(B) and (C), and  
23 it was a “prescription drug” within the meaning of 21 U.S.C. § 353(b). Actimmune® was not  
24 exempt under 21 C.F.R. § 201.115 from the requirement that it bear adequate directions for use  
25 for all of its intended uses.

26 8. Defendant InterMune contracted with a specialty pharmacy located in Florida to  
27 distribute Actimmune® to patients located in the Northern District of California and elsewhere.

28 9. From at least August 2002 until at least January 2003, in the Northern District of

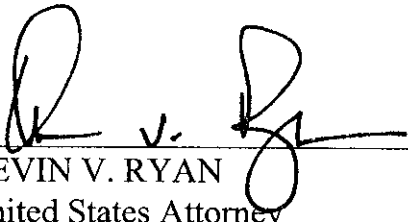
1 California and elsewhere, Defendant InterMune promoted Actimmune® for the treatment of  
2 idiopathic pulmonary fibrosis (IPF), a new intended use for Actimmune®, for which InterMune  
3 did not have an approved New Drug Application or effective Investigational New Drug  
4 application.

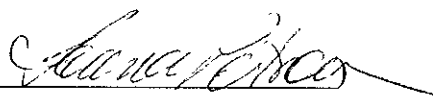
5 **COUNT ONE**

6 From in or about August 2002 until in or about January 2003, within the Northern District  
7 of California and elsewhere, the defendant INTERMUNE, INC., with the intent to defraud and  
8 mislead, promoted the drug Actimmune® for the treatment of idiopathic pulmonary fibrosis, a  
9 condition for which it was not approved by FDA, while the drug was held for sale after shipment  
10 in interstate commerce, which resulted in the drug being misbranded within the meaning of 21  
11 U.S.C. § 352(f)(1), in that its labeling did not bear adequate directions for use, all in violation of  
12 21 U.S.C. §§ 331(k) and 333(a)(2).

13  
14 DATED: October 24, 2006

United States Attorney  
KEVIN V. RYAN

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19 KEVIN V. RYAN  
United States Attorney

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21 (Approved as to form:   
22 AUSA IOANA PETROU  
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that he is an employee of the office of the United States Attorney, Northern District of California and is a person of such age and discretion to be competent to serve papers. The undersigned certifies that he caused copies of

INFORMATION

in the case of United States v. Intermune, Inc., No. TBD  
to be served on the parties in this action, addressed as follows which are the last known addresses and fax numbers:

**Barbara Hoffman**  
**Covington & Burling LLP**  
**1330 Avenue of the Americas**  
**New York, New York 10019**  
**212-841-1143**  
**Fax: 646-441-9143**  
**bhoffman@cov.com**

\_\_\_\_ (By Personal Service), I caused such envelope to be delivered by hand to the person or offices of each addressee(s) above.


\_\_\_\_ (By Facsimile), I caused each such document to be sent by Facsimile to the person or offices of each addressee(s) above.

\_\_\_\_ (By Mail), I caused each such envelope, with postage thereon fully prepaid, to be placed in the United States mail at San Francisco, California.

X  (By Fed Ex), I caused each such envelope to be delivered by FED EX to the address listed above.

I declare under penalty of perjury that the foregoing is true and correct.

October 26, 2006

  
TYLER L. DOERR  
United States Attorney's Office